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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,761	08/24/2006	Harukazu Kitagawa	58270/A400	7304

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EXAMINER	
EPPS SMITH, JANET L	

ART UNIT	PAPER NUMBER
1633	

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04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,761	KITAGAWA ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 4, 6 and 8 are presently pending for examination.

Specification

2. The substitute specification filed 6-12-08 has been entered in response to Applicant's reply filed 11/24/2008. Applicant's reply filed 11/24/2008 requested that the set of claims listed in the Substitute Specification be removed. Applicants further requested that the amended set of claims filed 6-12-08 be examined.

Response to Arguments

Claim Rejections - 35 USC § 102

3. The rejection of claims 1, 4, 6 and 8 under 35 U.S.C. 102(b) as being anticipated by Bachmann et al. (US2003091593 A1; entire document); the rejection of claims 1, 4, 6, and 8 under 35 U.S.C. 102(b) as being anticipated by Bachmann et al. (2003/0099668 A1; entire document); and the rejection of claims 1, 4, 6 and 8 are under 35 U.S.C. 102(b) as being anticipated by Takauji et al. (2002), are withdrawn in response to Applicant's amendment to the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokunaga et al. (EP468520A2-January 29, 1992) in view of Kaji et al. (WO2002/02172A1-January 10, 2002).

Tokunaga et al. describe single-stranded immunostimulatory oligonucleotides comprising a palindromic structure. In a preferred embodiment, an oligonucleotide having the nucleotide sequence "GACGATCGTC," is disclosed, see page 3, lines 45-50. Tokunaga et al. also describe the oligonucleotides of their invention in the following manner:

Page 4, lines 39-47:

> These DNAs may also be used in the form of medicinally approved salts. For example, sodium salts can be obtained by adding sodium hydroxide to an aqueous solution of DNA of this invention to adjust the pH to 7, followed by lyophilization. These DNAs may also be used as a complex with a polycationic compound, such as poly-L-lysine (hereinafter abbreviated as PLL). Such complex can be prepared, for example, by mixing an aqueous solution of DNA of this invention with an aqueous solution of PLL so that the DNA-PLL weight ratio will be about 4:3.
>
> The immunostimulatory remedies of this invention may be used alone or in combination with other therapeutic means against such diseases the outbreak of which can be suppressed, or the progress of which can be arrested or delayed, by the functions of the immune system. As examples of such diseases,

Page 5, lines 29-36:

> DNAs of this invention enhance the production of interferon and macrophage activating factor, thus activating NK cells and macrophages, also enhance the production of colony-stimulating factor, promote the proliferation of lymphocytes, and are therefore considered to exhibit a wide range of immunostimulatory activity. In addition, these DNAs proved to be very efficacious remedies against experimental tumors, and experimental models for immunodeficiency diseases and for autoimmune diseases, through their immunostimulatory activity. Furthermore, the acute toxicity of these DNAs is much lower than that of synthetic RNA; thus these DNAs are expected to be highly efficacious and useful remedies against malignant tumors, various auto-immune diseases, immunodeficiency diseases and infectious diseases.

However, Tokunaga et al. does not teach the modification of their disclosed immunostimulatory oligonucleotides comprising a palindromic sequence by the addition of 10 Guanine residues.

Kaji et al. teach the design of palindromic oligonucleotides for stimulating an immune response, wherein the palindromic oligonucleotide sequences are flanked by up to 11 Guanylic acid residues. According to Kaji et al. introduction of no more than 10 guanylic acid residues on either end of a palindrome structure results in stimulation of the cytokine induction of the palindrome sequence.

Kaji et al. also teach pharmaceutical compositions comprising the immunogenic guanylic acid palindrome modified oligonucleotides in combination with a tumor antigen, a viral antigen, an allergen or a microbial antigen.

It would have been obvious to the ordinary skilled artisan to modify the palindromic oligonucleotides of Tokunaga et al. with no more than 10 guanine residues based upon the teachings of Kaji et al. One of ordinary skill in the art would have motivated to make this modification since Kaji et al. teach that introduction of no more than 11 guanylic acid residues on either end of a palindrome structure results in stimulation of the cytokine induction of the palindrome sequence. Therefore, the ordinary skilled artisan seeking alternative immunostimulatory sequences would have been motivated to review the prior art and would have identified the palindrome sequence of Tokunaga et al. as a preferred immunostimulatory sequence, and would have further been motivated to modify this sequence as per the teachings of Kaji et al. and would have identified the sequence of SEQ ID NO: 19 recited in the instant claims, as a modification of the Tokunaga et al. palindrome sequence having no more than 11 guanine residues on either end of the sequence.

Regarding the rationale for combining prior art elements according to known methods to yield predictable results, all of the claimed elements were known in the prior art and one skilled in the art could have combined the element as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Moreover, since the prior art clearly disclosed the palindromic oligonucleotide sequence of "GACGATCGTC," and further taught that modifying this sequence by the addition of no more than 11 guanylic acid residues would increase the cytokine induction of the oligonucleotide, absent evidence to the contrary, as per MPEP § 2144.05 [R-5] "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the instant case, it would have been obvious to vary the number of guanylic acid residues which flank the prior art palindromic sequence.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633